

### ***Remarks***

Applicants respectfully request that the present remarks be entered and made of record in the instant application. Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 18-19, 22, 24, 30-32 and 35-37 are pending in the application, with claims 32, 36 and 37 being the independent claims. Claims 33-34 are sought to be canceled. Claim 32 is sought to be amended. Claims 36 and 37 are sought to be added. No new matter is added by way of these amendments. It is respectfully requested that the amendments be considered and entered.

Support for the amendment of claim 32 and new claims 36 and 37 can be found, *inter alia*, throughout the specification, *e.g.*, page 13, line 14 to page 14, line 12; page 14, lines 20-26; page 16, lines 16-18; Table 1; and Figures 3 and 4.

### ***I. Objections***

#### ***A. Title***

The Examiner objected to the title “because of misspelling or typographical error”. (Office Action, page 2.) Applicants thank the Examiner for noting the error. Applicants have amended the title to correct the error. Therefore, Applicants respectfully request the Examiner reconsider and withdraw the rejection.

#### ***B. Information Disclosure Statement***

The Examiner states “[r]eference AW has been considered to the extent possible; however, it has been lined through and will not be included on the face of the file, as this document is not publicly available.” (Office Action, page 2.) Applicants respectfully disagree.

Reference AW is U.S. patent application 11/045,031 (the '031 application). The '031 application is publicly available via the United States Patent and Trademark Office's Patent Application Information Retrieval on the internet. Therefore, Applicants request that the Examiner indicate that the '031 application will be included on the face of the file. It is Applicants understanding that the '013 application has been fully considered by the Examiner.

## ***II. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph***

Claims 18-19, 22, 24, and 30-35 "are rejected under 35 U.S.C., [sic] second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (Office Action, page 3.) The Examiner states,

[t]he minimum requirements for method steps include a contacting step . . . in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized, and a correlation step describing how the results of the assay allow for the determination, which is recited in Claim 34. Furthermore, there is no concluding step recited for any of the claims 32-34.

(Office Action, page 3; underlining added.) Applicants respectfully disagree. However, solely to advance prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended claim 32 to address the Examiner's concerns by incorporating the subject matter of claims 33 and 34.

With regards to a "contacting step", Applicants believe that parts (a) and (c) of claim 32 constitute what the Examiner is referring to as a contacting step. With regards to a "detection step", Applicants believe that parts (b) and (d) of claim 32 constitute what the Examiner is referring to as a detection step. With regards to a "correlation step", Applicants believe that part (e) of claim 32 constitutes what the Examiner is referring to as a correlation step. With regards to

a “conclusion step”, Applicants believe that part (e) of claim 32 constitutes what the Examiner is referring to as a conclusion step.

Language similar to the above is also present in new claims 36 and 37.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, second paragraph.

### ***III. Claim Rejections Under 35 U.S.C. § 103***

#### ***A. Claims 18, 24 and 32-35***

Claims 18, 24 and 32-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolger *et al.* (PCT Publication No. WO 98/05962) in view of Roeder *et al.* (U.S. Patent No. 6,248,520), Burbaum *et al.* (U.S. Patent No. 5,876,946), and Kirkemo *et al.* (U.S. Patent No. 4,510,251). (Office Action, pages 3-4.) Applicants respectfully disagree.

Applicants assert that to establish a *prima facie* case of obviousness, the Examiner must, *inter alia*, show that the references upon which she or he relied teach every limitation of the currently claimed invention. (*In re Royka*, 490 F.2d 981, 985 (Fed. Cir. 1974).)

The Examiner alleges that Kirkemo *et al.* “teaches a pregn-4-ene-3,20-dione derivatized at the 3’ position with a animomethylfluorescein derivative (column 8, example 4, compound 4).” (Office Action, page 6.) Applicants respectfully disagree.

Compound 4 of Kirkemo *et al.* is not a pregnen. Compound 4 is a pregnane, specifically 11,17,21-trihydroxypregnane-3,20-dione. A 4-pregnen is characterized, *inter alia*, by a double bond between the carbon atoms at positions 4 and 5, whereas a pregnane has a single bond in this

position. Hence, Kirkemo *et al.* does not disclose a 4-pregnen derivatized at one or more of the 6, 7, 11, 17, 19, 20 or 21 positions with a linker conjugated to a fluorescent label, which is part of the subject matter of claim 32. Therefore, Kirkemo *et al.* does not disclose the steroids recited in the wherein clause of claim 32. Further, Bolger *et al.*, Roeder *et al.*, and Burbaum *et al.* do not cure this deficiency.

***B. Claim 19***

Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolger *et al.* in view of Roeder *et al.*, Burbaum *et al.* and Kirkemo *et al.* as applied to claim 32 and further in view of Chen (U.S. Patent No. 6,054,295). (Office Action, page 7.) Applicants respectfully disagree.

As discussed above, none of Bolger *et al.*, Roeder *et al.*, Burbaum *et al.* or Kirkemo *et al.* discloses the steroids recited in the wherein clause of claim 32. Chen does not cure this deficiency.

***C. Claims 22 and 30***

Claims 22 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolger *et al.* in view of Roeder *et al.*, Burbaum *et al.* and Kirkemo *et al.* as applied to claim 32 and further in view of Tanaka *et al.* (*Glia* 20:23-27, 1997). (Office Action, page 7.) Applicants respectfully disagree.

As discussed above, none of Bolger *et al.*, Roeder *et al.*, Burbaum *et al.* or Kirkemo *et al.* disclose the steroids recited in the wherein clause of claim 32. Tanaka *et al.* does not cure this deficiency.

***D. Claim 31***

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bolger *et al.* in view of Roeder *et al.*, Burbaum *et al.* and Kirkemo *et al.* as applied to claim 32 and further in view of Nath *et al.* (*Arch. Biochem. Biophys.* 292:303-310, 1992). (Office Action, page 8.) Applicants respectfully disagree.

As discussed above, none of Bolger *et al.*, Roeder *et al.*, Burbaum *et al.* or Kirkemo *et al.* disclose the steroids recited in the wherein clause of claim 32. Nath *et al.* does not cure this deficiency.

Therefore, since not all elements of the currently presented claims are taught or suggested by the cited references, a *prima facie* case of obviousness has not been established and Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103(a).

***Conclusion***

It is not believed that extensions of time are required beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, The United States Patent and Trademark Office is hereby authorized to charge any fee deficiency required to prevent abandonment of the current application or credit any overpayment to Deposit Account 13-3900.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and

complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,



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